SEP 25 1998

F: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

1)	Submitter:	Dexide, Inc. 7509 Flagstone Drive Fort Worth, TX 76118-6995 Phone No.: (817) 589-1454
	Contact Person:	Lynette Caldwell Director of Quality Assurance
	Date Prepared:	Friday, May 29, 1998
2)	Name of Device:	MultApump™ System
	Common Name:	Irrigation Pump
3)	Predicate Device:	Davol (Bard) –K961492
4)	Description of Device:	The "candidate device" consists of a Disposable Pump Head, pump motor, clamp & bracket, power supply and power cord(s) for use in laparoscopy. The Disposable Pump Head is a sterile, single-use device, composed of Stainless Steel, glass filled Polypropylene, Medical Grade EPDM, ABS plastic, plastic and flexible PVC tubing. It has an interface dock for attachments of the reusable pump motor. The pump motor, clamp, power supply and power cord are reusable components.
5)	Intended Use:	The "candidate device" is designed to be used in conjunction with a laparoscopic irrigation/suction device to provide controlled powered irrigation during laparoscopic surgical procedures.

6) Technological characteristics the candidate device is comparable to the predicate device in that both devices provide controlled powered irrigation during laparoscopic surgical procedures.

SECTION G:

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notification for tier 2 devices)

STATEMENT OF INDICATIONS FOR USE: The "candidate device" is designed to be used in conjunction with a laparoscopic irrigation/suction device to provide controlled powered irrigation during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

CLAIMS: The pump motor, clamp, bracket, power supply and power cord are reusable components. The Disposable Pump is supplied as a sterile, single-use product.

This notification contains all of the information required by 21 CFR 807.87.
A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

The candidate device conforms to the following voluntary and mandatory standards:

There are no existing mandatory performance standards that Dexide, Inc is aware.

The candidate device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the candidate device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)'s. The kit contains no drug or biologic products.

The above statements are accurate representations of this 510(k) Premarket Notification and of the device this firm intends to market. All data and information submitted in this Premarket Notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(J)).

MANUFACTURER: Dexide, Inc.
OFFICIAL CORRESPONDENT: Lynette Caldwell (signature)
Lynette Caldwell (printed name)
TITLE: Director of Quality Assurance
DATE: August 4, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

Ms. Lynette Caldwell
Director of Quality Assurance
Dexide, Inc.
7509 Flagstone Drive
Fort Worth, TX 76118-6995

Re: K981940
Trade Name: MultApump Disposable Pump Head and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 10, 1998
Received: August 21, 1998

Dear Ms. Caldwell:

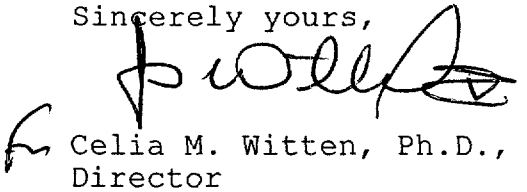
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981940

Device Name: MultApump™ System

Intended Use:

The MultApump™ System is designed to be used in conjunction with a laparoscopic irrigation/suction device to provide controlled powered irrigation during laparoscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981940

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96) __